

Application Number 10/698,291
Amendment in Response to Office Action mailed January 11, 2006

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AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claim 1 (Original): A neurostimulation lead comprising:
a lead body having a proximal end and a distal end;
one or more stimulation electrodes disposed adjacent the distal end of the lead body; and
a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site.

Claim 2 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes an elastic material.

Claim 3 (Original): The neurostimulation lead of claim 1, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 4 (Previously Presented): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a shape memory alloy.

Claim 5 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a super-elastic material.

Claim 6 (Original): The neurostimulation lead of claim 4, wherein the shape memory alloy includes Nitinol.

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Claim 7 (Original): The neurostimulation lead of claim 1, further comprising an inner lumen to accommodate a stylet.

Claim 8 (Original): The neurostimulation lead of claim 1, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 9 (Original): The neurostimulation lead of claim 8, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 10 (Original): The neurostimulation lead of claim 8, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

Claim 11 (Original): The neurostimulation lead of claim 1, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 12 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 13 (Original): The neurostimulation lead of claim 1, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 14 (Original): The neurostimulation lead of claim 1, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 15 (Original): The neurostimulation lead of claim 1, wherein the one or more electrodes include at least four electrodes.

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Claim 16 (Original): The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 17 (Original): The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 18 (Original): The neurostimulation lead of claim 1, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 19 (Original): The neurostimulation lead of claim 1, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 20 (Original): The neurostimulation lead of claim 1, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 21 (Original): The neurostimulation lead of claim 1, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 22 (Original): A neurostimulation system comprising:

- an implantable neurostimulation pulse generator;
- a lead body having a proximal end and a distal end;
- one or more stimulation electrodes disposed adjacent the distal end of the lead body;
- an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes; and
- a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site.

Claim 23 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements includes an elastic material.

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Claim 24 (Original): The neurostimulation system of claim 22, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 25 (Previously Presented): The neurostimulation system of claim 22, wherein each of the wire-like elements includes a shape memory alloy.

Claim 26 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements includes a super-elastic material.

Claim 27 (Original): The neurostimulation system of claim 25, wherein the shape memory alloy includes Nitinol.

Claim 28 (Original): The neurostimulation system of claim 22, further comprising an inner lumen to accommodate a stylet.

Claim 29 (Original): The neurostimulation system of claim 22, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 30 (Original): The neurostimulation system of claim 29, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 31 (Original): The neurostimulation system of claim 29, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

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Claim 32 (Original): The neurostimulation system of claim 22, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 33 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 34 (Original): The neurostimulation system of claim 22, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 35 (Original): The neurostimulation system of claim 22, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 36 (Original): The neurostimulation system of claim 22, wherein the electrodes include at least four electrodes.

Claim 37 (Original): The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 38 (Original): The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 39 (Original): The neurostimulation lead of claim 22, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 40 (Original): The neurostimulation lead of claim 22, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 41 (Original): The neurostimulation system of claim 22, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

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Claim 42 (Original): A method comprising:

inserting a lead introducer into a patient;

inserting a lead into the patient via the introducer, wherein the lead includes a lead body having a proximal end and a distal end, one or more stimulation electrodes disposed on the lead body, and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site; and

removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand.

Claim 43 (Original): The method of claim 42, wherein removing a restraint includes withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand.

Claim 44 (Original): The method of claim 42, wherein removing a restraint includes withdrawing at least a portion of the lead introducer, thereby releasing the fixation mechanism to expand.

Claim 45 (Original): The method of claim 42, further comprising:
detaching a distal end of each wire-like element; and
withdrawing the lead from the target site.

Claim 46 (Original): The method of claim 42, further comprising:
restraining the expanded fixation mechanism; and
withdrawing the lead from the target site.

Claim 47 (Original): The method of claim 42, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

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Claim 48 (Original): The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 49 (Original): The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 50 (Original): The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 6 to 15 mm.

Claim 51 (Original): The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 9 to 12 mm.

Claim 52 (Original): The method of claim 42, wherein each of the wire-like elements includes an elastic material.

Claim 53 (Previously Presented): A stimulation lead comprising:
a lead body having a proximal end and a distal end;
one or more stimulation electrodes disposed on the lead body; and
means for fixing the lead body relative to tissue proximate a target stimulation site,
wherein the fixing means includes wire-like elements that are expandable to fix the lead body at a tissue target site, and wherein the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body.

Claim 54 (Original): The lead of claim 53, wherein each of the wire-like elements includes an elastic material.

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Claim 55 (Original): The lead of claim 53, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 56 (Previously Presented): The lead of claim 53, wherein each of the wire-like elements includes a shape memory alloy.

Claim 57 (Original): The lead of claim 53, wherein each of the wire-like elements includes a super-elastic material.

Claim 58 (Original): The lead of claim 53, further comprising means for restraining the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraining means.

Claim 59 (Original): The lead of claim 53, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 60 (New): The neurostimulation lead of claim 1, further comprising a plurality of retainer rings, wherein the retainer rings mount the wire-like elements to the lead body at proximal ends and distal ends of the wire-like elements

Claim 61 (New): The neurostimulation lead of claim 1, wherein the fixation mechanism is spring-biased.

Claim 62 (New): The neurostimulation system of claim 32, wherein the stylet provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion.

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Claim 63 (New): The neurostimulation system of claim 62, wherein the elastic portion of the lead body decreases in length upon removal of the stylet.